REMARKS/ARGUMENTS

The Pending Claims

Claims 1-53 are pending and are directed to a method of increasing the bioavailablility of the active form of *S*-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate (claims 1-15), a method of increasing the extent of absorption of the active form of *S*-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate (claims 16-24), a method for decreasing the activity of CETP in a patient (claims 25-33), a method for the treatment of a cardiovascular disorder (claims 34-43), and a kit comprising a pharmaceutical composition comprising *S*-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate (claims 44-53).

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the present invention. In particular, claims 1, 16, 25, 34, and 44 have been amended to recite that the food is not part of the pharmaceutical composition, as supported by the specification at, for example, paragraphs [0024] and [0044] and Example 1. No new matter has been added by way of these amendments.

Summary of the Office Action

Applicants thank the Office for the withdrawal of the previous rejection of (i) claims 34-43 under 35 U.S.C. § 112, first paragraph, and (ii) claims 1-6, 10, 16-21, 25-30, and 34-40 under 35 U.S.C. § 102(b) as anticipated by Okamoto et al. (*Nature*, 406(13): 203-207 (2000)).

The Office objects to claims 48-50 for allegedly being in improper dependent form.

The Office rejects claims 1-6, 10, 16-21, 25-30, and 34-40 under 35 U.S.C. § 102(e) as allegedly anticipated by Gumkowski et al. (U.S. Patent Application Publication 2006/0014788). The Office rejects claims 1-10 and 16-43 under 35 U.S.C. § 102(a) as allegedly anticipated by Shinkai et al. I (U.S. Patent 6,426,365).

The Office rejects claims 1-6, 10-21, 25-30, 34-40, and 44-50 under 35 U.S.C. § 103(a) as allegedly unpatentable over Gumkowski et al. in view of Remington's Pharmaceutical Sciences. The Office rejects claims 1-53 under 35 U.S.C. § 103(a) as allegedly unpatentable over Shinkai et al. I in view of Remington's Pharmaceutical Sciences.

The Office rejects claims 1-53 on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-24 of Shinkai et al. I or claims 1-17 of Shinkai et al. II (U.S. Patent 6,753,346). The Office provisionally rejects claims 1-53 on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over (a) claims 1-18 of co-pending U.S. Patent Application 10/825,531, (b) claims 1-9 and 11-23 of co-pending U.S. Patent Application 10/802,220, and (c) claims 1-5, 7-32, 34-52, and 54-83 of co-pending U.S. Patent Application 10/835,916.

Discussion of the Claim Objections

The Office objects to claims 48-50 for allegedly being in improper dependent form for failing to limit the subject matter of a previous claim. With respect to the previous amendments to claims 48-50, the Examiner states "[s]uch is not deemed to be further limiting of the kit of claim 40" (Office Action, fourth line from bottom of page 2). Claim 40 is directed to a method for the treatment of a cardiovascular disorder and not to a kit. Moreover, kit claims 48-50 are not dependent on method claim 40. Therefore, the bases of the objections to kit claims 48-50 is unclear to Applicants. Applicants respectfully request further clarification of these objections.

Discussion of the Anticipation Rejections

The Office has rejected the claims as allegedly anticipated in view of several references. These rejections are traversed for the following reasons.

A. Gumkowski et al.

The anticipation rejection over Gumkowski et al. is moot in view of the Declaration under 35 C.F.R. § 1.131 of Yasuo Urata and Tomohiro Ishikawa submitted herewith. The Rule 131 Declaration establishes conception and reduction to practice of the invention recited in the pending claims prior to the earliest possible section 102(e) date of Gumkowski et al.

(i.e., June 21, 2001). As such, Gumkowski et al. is not prior art to the present application under section 102(e), and it is not prior art to the present application under any other subsection of section 102. As a result, this rejection should be withdrawn.

B. Shinkai et al. I

The Office contends that, while Shinkai et al. I does not expressly teach that the compound is administered with food, ingredients in the pharmaceutical compositions, such as lactose and starch, allegedly qualify as foods, such that Shinkai et al. I anticipates the claims (pages 15-16 of Office Action issued March 31, 2006).

The Rule 131 Declaration submitted herewith establishes that the subject matter of the pending claims was conceived of and reduced to practice prior to June 21, 2001. As a result, Shinkai et al. I is not prior art to the present application under section 102(a). However, the corresponding international patent application (i.e., WO 98/35937, already of record) published more than one year prior to the earliest priority date of the present application (i.e., August 20, 1998). To the extent that WO 98/35937 is in Japanese and has the same disclosure as Shinkai et al. I, the following discussion is based on both documents.

The claims have been amended to further clarify that the food is not part of the pharmaceutical composition comprising S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate. In other words, the claims require that the food administered to the patient is separate from (i.e., not part of) the pharmaceutical composition comprising S-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate. Since the lactose and starch bulking agents disclosed in Shinkai et al. are part of the pharmaceutical composition, these materials do not meet the definition of "with food" as utilized in the pending claims. As such, Shinkai et al. I and WO 98/35937 do not anticipate the subject matter of the pending claims, and the anticipation rejection in view thereof should be withdrawn.

Discussion of the Obviousness Rejections

The Office rejects the claims as allegedly obvious in view of Gumkowski et al. or Shinkai et al. I for those reasons discussed above corresponding to the anticipation rejections

and further in view of Remington's Pharmaceutical Sciences. The Office concedes that Gumkowski et al. and Shinkai et al. I do not disclose providing the composition to a patient in a container associated with prescribing information (such as a kit), but the Office contends that Remington's Pharmaceutical Sciences discloses labeling instructions (e.g., for a kit). The Office also concedes that Gumkowski et al. and Shinkai et al. I do not disclose the dosages recited in claims 2, 3, 17, 18, 26, 27, 36, and 37, but the Office contends that it would be within the skill of an ordinary artisan to discover optimum or working ranges by routine experimentation. Applicants traverse these rejections for the following reasons.

A. Gumkowski et al. & Remington's Pharmaceutical Sciences

As discussed above, Gumkowski et al. is not prior art to the present application in view of the Rule 131 Declaration submitted herewith, which establishes conception and reduction to practice of the invention recited in the pending claims prior to the earliest possible section 102(e) date of Gumkowski et al. (i.e., June 21, 2001). As such, Gumkowski et al. is not prior art to the present application under section 102(e), and it is not prior art to the present application under any other subsection of section 102. Moreover, the disclosure of Remington's Pharmaceutical Science alone fails to teach each and every element of the claims. Accordingly, the obviousness rejection based on Gumkowski et al. and Remington's Pharmaceutical Sciences is moot and should be withdrawn.

B. Shinkai et al. I & Remington's Pharmaceutical Sciences

As discussed above, neither Shinkai et al. I nor WO 98/35937 teaches or suggests administering the *S*-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate pharmaceutical composition with food, in which the food is not part of the pharmaceutical composition. Moreover, the disclosure of lactose and starch bulking agents (which are identified as "food" by the Office) as part of the pharmaceutical composition disclosed in Shinkai et al. I or WO 98/35937 would not have suggested to one of ordinary skill in the art to administer the pharmaceutical composition with food, in which the food is not part of the pharmaceutical composition (i.e., where food is separate from the pharmaceutical composition). Without such a suggestion to modify the disclosure of Shinkai et al. I or WO 98/35937, the present invention cannot be considered obvious in view of these references.

Moreover, Remington's Pharmaceutical Sciences does not remedy the aforesaid deficiencies of Shinkai et al. I and WO 98/35937. Thus, even if combined, the cited references do not disclose every element of any of claims 1-53. As a result, in view of the claim amendments, the obviousness rejection in view of Shinkai et al. I and Remington's Pharmaceutical Sciences is without merit and should be withdrawn.

Discussion of the Obviousness-type Double Patenting Rejections

The Office has rejected the claims for obviousness-type double patenting in view of several references. These rejections are traversed for the following reasons.

A. Shinkai et al. I or Shinkai et al. II

Shinkai et al. I contains only compound claims that encompass the species of the compound recited in the pending method claims.

Shinkai et al. II contains claims directed to *S*-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate, as well as a method of inhibiting CETP activity, a method of increasing HDL, a method of decreasing LDL, a method of treating or preventing atherosclerosis, and a method of treating or preventing hyperlipidemia.

The claims of the cited patents do not teach or suggest a method comprising administering a pharmaceutical composition comprising *S*-[2-([[1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate with food, wherein the food is not part of the pharmaceutical composition, as recited in the amended pending claims.

Accordingly, the subject matter of the pending claims cannot be considered obvious in view of the claims of the cited patents, and the obviousness-type double patenting rejections based on the foregoing patents should be withdrawn.

B. *U.S. Patent Application 10/825,531, U.S. Patent Application 10/802,220, or U.S. Patent Application 10/835,916*

The obviousness-type double patenting rejections based on these pending applications are "provisional," and Applicants will address the rejections at which time the cited applications issue as patents and the rejections become non-provisional.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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